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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/087,355 | 03/01/2002 | Richard C. Boucher JR. | 5470.250DV | 3423 |
| 20792 | 7590 | 08/16/2005 | EXAMINER | |
| MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627 | | | WANG, SHENGJUN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |

DATE MAILED: 08/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,355

Applicant(s)

BOUCHER, RICHARD C.

Examiner

Shengjun Wang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14,15,20,31-39,41-43 and 50-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14,15,20,31-39,41-43 and 50-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of applicants' amendments and remarks submitted June 11, 2005 is acknowledged.

Note the claims have been examined insofar as they read on elected invention and species (see paper submitted October 10, 2002 for elected invention and species).

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 14, 15, 20, 31-44 and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (U.S. Patent 5,863,563, of record) in view of Cropp and Glass (U.S. Patent 5,162,348, of record).

3. Scheele teaches a method for treating symptom of a patient who has pulmonary conditions, including cystic fibrosis, the method comprising causing the patient inhale a composition comprising alkali metal salts, such as potassium salt or sodium salts. Various anions may be employed, including bicarbonate. See, column 5, line 52 bridging column 6, line 18, and the claims.

4. Scheele does not teach expressly the employment of combination of salts, or the further employment of bronchodilator in the composition.

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5. However, Cropp and Glass teach that bronchodilators are well known to be useful for treating cystic fibrosis, particularly administered in aerosolized forms. The well-known bronchodilators include isoproterenol, metaproterenol. See, particularly, the abstract, table IV in Cropp and column 1, lines 44-51 in Glass. Glass further suggests that bronchodilators may be employed with other agents useful for treating cystic fibrosis.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with well-known bronchodilator before administering the instant composition.

A person of ordinary skill in the art would have been motivated to employ more than one of the known salts disclosed by Scheele in the therapeutical composition, or treating the patient with bronchodilator before administering the instant composition because all the salts disclosed by Scheele are known to be similarly useful in treating cystic fibrosis and it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. The combining treatment with bronchodilator is also obvious since bronchodilator is known to be useful for treating cystic fibrosis. The optimization of a result effective parameter, e.g., the method of administering two agents, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. The examiner assumes that claim 37, as amended, would still read on the elected potassium bicarbonate, absent an indication to the contrary.

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6. Claims 14, 15, 20, 31-44 and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (U.S. Patent 5,863,563, of record) in view of Cropp and Glass (U.S. Patent 5,162,348, of record), in further view of Robinson et al. (IDS)

7. The claims are obvious over Scheele, Cropp and Glass for reasons discussed above. Robinson et al. provide further motivation to combine the cited references thereby reach the claimed invention. Robinson et al. teach that applying hypertonic solution to lung surface are beneficial to improve the lung function of cystic fibrosis patients and further suggest its combination with bronchodilator. 1507 to 1508, particularly, the last two paragraphs at page 1508. One of ordinary skill in the art, would have been further motivated to combine a hypertonic solution, such as those disclosed by Scheele with a bronchodilator for treatment of cystic fibrosis patients because of the benefit suggested by Robinson et al.

Response to the Arguments

Applicants' amendments and remarks submitted June 11, 2005 have been fully considered, but are found unpersuasive.

Applicants contend that the rejections of the claimed invention over Scheele et al. is improper because Scheele is mischaracterized. Specifically, applicants contend Scheele et al. teach pH-raising buffer, in contrasting to osmotically active compound herein recited. The arguments are unpersuasive. Note Scheele et al. teach the exactly same agents herein employed, e.g., alkali metal salts, such as potassium salt or sodium salts. Citing different function, i.e., "osmotically active" of the compounds do not change the fact that the same compounds are known to be useful for treating symptom of a patient who has pulmonary conditions, including cystic fibrosis. Any properties exhibited by or benefits provided the composition are inherent and

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are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical compounds, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990. See MPEP 2112.01.

Applicants further argue that the combination of the references do not teach the claimed invention, particularly, “osmotically active compound”. It is noted the elected salt(s) is potassium carbonate, which is disclosed by Scheele et al as useful for treating pulmonary conditions, including cystic fibrosis. As to claim 37, do not clearly point out whether the claim read on the elected species. The examiner assumes that claim 37, as amended, would still read on the elected potassium bicarbonate, absent an indication to the contrary. If claim 37 does not read on the elected species, it is not rejected as it drawn to non elected species.

8. With respect to the rejections over Scheele (U.S. Patent 5,863,563, of record) in view of Cropp and Glass (U.S. Patent 5,162,348, of record), in further view of Robinson et al. (IDS), applicants argue that “pH-raising buffers” as disclosed by Scheele et al. is not hypertonic solution as required by Robinson et al. The arguments are not persuasive. Applicants’ attention is directed to column 5, lines 14-30, and the claims in Scheele et al. note the so called “pH-raising buffer” is actually a highly concentrated composition, or preferably, dry powder, which, when in contact with the aqueous solution bathing the interior of the alveolus, will raise the pH of the solution at least about 0.1 pH. Such high concentrated composition would have been obvious to one of ordinary skill in the art as being hypertonic.

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9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

~~SHENGJUN WANG~~
PRIMARY EXAMINER
Shengjun Wang
Primary Examiner
Art Unit 1617